



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/527,781

03/31/2006

Robert Savit

UM-09752

9565

72960

7590

12/08/2009

Casimir Jones, S.C.

2275 DEMING WAY, SUITE 310

MIDDLETON, WI 53562

EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,781	Applicant(s) SAVIT ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 September 2009 has been entered.

Claim Objections

3. Claim 1 is objected to because of the following informalities: There is no antecedent basis for "the focal point". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. Claims 1-3, 5-14, and 16-21 rejected under 35 U.S.C. 102(e) as being anticipated by Sackellares (US 2004/0122335).

Regarding claim 1, Sackellares discloses a system for predicting ictal onset in a subject comprising first and second data sensors configured to be positioned on the scalp of a subject, where one is near an ictal onset focal point and the other is remote

Art Unit: 3735

from the first sensor (figures 4A and 4B; paragraphs [0078]-[0079]), and a processor configured to analyze data collected at more than one time point from the sensors (paragraph [0026]; element 1210), where the sensor performs nonlinear manipulation of the data to produce a plurality of marginal predictability values for each time point, and the processor is configured to determine the difference between the marginal predictability values (paragraphs [0025], [0026], [0040], [0045], [0055]-0057], [0069]), where a decrease in the difference between values is predictive of ictal onset (entire document, with particular emphasis on paragraphs [0089], [0096], [0101]). The Examiner notes that Applicant has not provided a specific definition for "near" - given that Sackellares provides a plurality of electrodes on the subject's scalp, any one of them may be considered "near" a focal point. The Examiner also notes that divergence is the opposite of convergence (entrainment), so a decrease in divergence is the same as an increase of convergence.

Regarding claim 2, Sackellares further discloses the sensors comprising electrodes (paragraphs [0078]-[0079]).

Regarding claim 3, Sackellares further discloses the electrodes being used to record electroencephalogram data from the subject (paragraph [0040]).

Regarding claim 5, Sackellares further discloses collecting data at at least three time points (figure 2).

Regarding claims 6 and 7, Sackellares further discloses a subject warning device configured to receive information predictive of an ictal onset from the processor (paragraphs [0024], [0047])

Regarding claim 8, Sackellares further discloses the warning device comprising at least one audible or visual alarm (paragraph [0095]).

Regarding claim 9, Sackellares further discloses the processor comprising a computer readable memory (paragraph [0050]).

Regarding claim 10, Sackellares further discloses an anti-seizure agent administering device in communication with the processor that is configured to administer an anti-seizure agent to the subject (paragraphs [0103]-[0105]).

Regarding claim 11, Sackellares further discloses the anti-seizure agent being an electrical stimuli device (paragraph [0105]).

Regarding claim 12, Sackellares discloses a method of predicting ictal onset in a subject comprising providing a system with first and second data sensors configured to be positioned on the scalp of a subject, where one is near an ictal onset focal point and the other is remote from the first sensor (figures 4A and 4B; paragraphs [0078]-[0079]), and a processor configured to analyze data collected at more than one time point from the sensors (paragraph [0026]; element 1210), where the sensor performs nonlinear manipulation of the data to produce a plurality of marginal predictability values for each time point, and the processor is configured to determine the difference between the marginal predictability values (paragraphs [0025], [0026], [0040], [0045], [0055]-0057], [0069], [0089], [0096], [0101]), obtaining marginal predictability values for more than one time point, and determining the difference between the values, where a decrease in the difference between values is predictive of ictal onset (paragraphs [0089], [0096], [0101]). The Examiner notes that Applicant has not provided a specific definition for

Art Unit: 3735

"near" - given that Sackellares provides a plurality of electrodes on the subject's scalp, any one of them may be considered "near" a focal point. The Examiner also notes that divergence is the opposite of convergence (entrainment), so a decrease in divergence is the same as an increase of convergence.

Regarding claim 13, Sackellares further discloses the sensors comprising electrodes (paragraphs [0078]-[0079]).

Regarding claim 14, Sackellares further discloses the electrodes being used to record electroencephalogram data from the subject (paragraph [0040]).

Regarding claim 16, Sackellares further discloses collecting data at at least three time points (figure 2).

Regarding claims 17 and 18, Sackellares further discloses a subject warning device configured to receive information predictive of an ictal onset from the processor (paragraphs [0024], [0047])

Regarding claim 19, Sackellares further discloses the warning device comprising at least one audible or visual alarm (paragraph [0095]).

Regarding claim 20, Sackellares further discloses an anti-seizure agent administering device in communication with the processor that is configured to administer an anti-seizure agent to the subject (paragraphs [0103]-[0105]).

Regarding claim 21, Sackellares further discloses the anti-seizure agent being an electrical stimuli device (paragraph [0105]).

Claim Rejections - 35 USC § 103

Art Unit: 3735

5. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackellares, as applied above, and further in view of Boling (US 2003/0195602).

Sackellares discloses all the elements of the claimed inventions, as described above, except for the plurality of time points being separated by ten minute intervals. Boling teaches measuring biosignals to predict an ictal onset in a subject where the measurements are taken at time points separated by non-recording intervals (paragraphs [0203], [0207]), in order to reduce the amount of data captured by the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have configured the system of Sackellares to capture data at time points separated by non-recording intervals, as taught by Boling, in order to reduce the data captured by the system. The Examiner notes that Sackellares and Boling do not expressly disclose the interval between measurements being ten minutes; at the time the invention was made, it would have been an obvious matter of design choice for a person of ordinary skill in the art to separate measurements by ten minutes because the Applicant has not disclosed that the exact interval between measurements provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that the interval of Boling, or Applicant's interval, would perform equally well to minimize measurements. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Sackellares and Boling to take measurements at ten minute intervals, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Sackellares and Boling.

Response to Arguments

6. Applicant's arguments with respect to claims 1-3, 5-14, and 16-21 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner notes that Applicant did not provide any arguments related to Boling in the most recent response.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6304775 to Iasemidis, 7177108 to Rapp, and 6658287 to Litt, which disclose similar inventions.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735